# 1. Process Excellence & Continuous Improvement (OPEX)

- **Solvent Management & Recovery:** Work on the minimization of solvent losses in production blocks and separation processes (distillation, centrifugation, drying, and evaporation). Periodically monitor and review Solvent Recovery System (SRS) operations, occupancy, and recovery percentages. Propose new processes for recovery improvement, establish closed-loop washings, and evaluate solvent-wise material balances to reduce fresh solvent consumption.
- **Cycle Time Reduction:** Identify bottleneck operations to evaluate critical operations and reduce batch cycle times. Focus on time cycle reduction for unit operations like distillation, filtration, and drying through process modifications.
- **Yield & Productivity Optimization:** Drive process improvement activities including yields, cycle time, and productivity enhancement. Ensure budgeted yields are achieved and improved upon, and reduce process delay steps and yield losses.
- **Energy & Utility Optimization:** Identify the energy audit of the plant, estimate utility consumption variance, and handle water conservation and recycling projects.
- **Plant Capacity Release:** Governed site-level productivity improvement roadmaps across multi-product API lines; combined process intensification strategies and heat-exchanger modifications to deliver a continuous 10% to 11% expansion and release in total plant asset capacity (measured via Total KL Days).

# 2. Technology Transfer & Scale-Up

- **Technology Absorption:** Absorb technology from clients/customers or the R&D team to develop projects and extend batch monitoring support for successful plant execution.
- **Data Generation:** Generate scale-up data in the lab, including engineering parameters such as mixing calculations, rates of filtration, rates of heating/cooling, distillation times, reagent addition times, and utility calculations.
- **Scale-Up Operations:** Scale up newly developed APIs and intermediates from small-scale/lab/pilot scale to plant and commercial scale.
- **Documentation & Review:** Review technology transfer documents such as tech packs, CPHE reports, and engineering calculations (distillation rates, filtration/crystallization studies). Prepare validation Batch Production Record (BPR) documents and process engineering dockets.
- **Cross-Functional Liaison:** Coordinate with R&D, manufacturing, regulatory departments, and Quality Assurance (QA) for conducting validation batches and DMF filings. Raise scale-up concerns regarding process or chemistry to

group leaders during demonstrations or prior to scale-up.

# 3. Product Development & Process Engineering

- **Feasibility Studies:** Conduct new product process evaluations and assess the feasibility of handling hazardous chemicals at the lab scale.
- **Engineering Calculations:** Perform detailed material balance, energy balance, and mass balance calculations for each product. Perform basic chemical engineering calculations including heat load, utility requirements, line sizing, condenser capacity checking, and pump specifications.
- **Crystallization & Polymorph Studies:** Study crystallization processes to meet the desired polymorph or particle size distribution, and monitor batches to address abnormalities during crystallization.
- **Data Collection:** Perform mixing studies, corrosion studies (generating coupon test data), and powder safety studies.

# 4. Technical Services & Troubleshooting

- **Equipment & Facility Mapping:** Conduct facility identification, product mapping, and equipment mapping for executing pilot, commercial trial, and validation batches. Map circuits with the best fitment to de-clash the product matrix with alternate setups.
- **Troubleshooting:** Troubleshoot existing plant processes, daily production activities, and equipment issues to maintain desired yields, quality, and smooth plant operations.
- **Investigations (OOS/OOT/Deviations):** Provide technical support to investigate product failures, Out of Specification (OOS) results, Out of Trend (OOT) results, and process deviations. Perform detailed root-cause investigations and prepare formal reports with appropriate Corrective and Preventive Actions (CAPA) to eliminate repeat incidents.

# 5. Projects & Capital Expenditure (CAPEX)

- **Engineering Design:** Prepare Process Flow Diagrams (PFD), Piping and Instrumentation Diagrams (P&ID), and process data sheets for new or modified process equipment (reactors, filters, dryers, storage tanks).
- **Equipment Selection & Sizing:** Select and size process equipment using specialized calculations like power per unit volume, tip speed, and agitator power consumption. Prepare User Requirement Specifications (URS), Data Sheets, Design Qualification (DQ).
- **Utility Infrastructure Sizing:** Estimate utility consumption and size major infrastructure such as cooling towers, chilled water plants, brine plants, steam boilers, and utility header lines.
- **Erection & Commissioning:** Handle the erection, pre-commissioning, and commissioning of new process equipment, production blocks (including DCS systems), solvent recovery systems, and effluent treatment systems like Multiple Effective Evaporators (MEE) and Agitated Thin Film Dryers (ATFD).

- **Project Management & Costing:** Coordinate and execute new projects in the kilo lab or plant, interface with maintenance and plant engineering, and prepare detailed project cost estimations, RMC costing, and CAPEX requirements.

# 6. Process Safety:

- **Risk Assessments:** Identify process risks, hazards, and environmental aspects. Prepare and review Process Safety Information (PSI), Process Hazard Analysis (PHA), Pre-Start Safety Review (PSSR), and Quantitative Risk Assessment (QRA).
- **HAZOP Studies:** Participate in or lead Hazard and Operability (HAZOP) studies for new products with Cross-Functional Teams (CFT) to implement necessary mitigation measures.
- **Operational Safety & Compliance:** Ensure all production processes are risk-assessed for personnel and environmental safety. Close Safety Observation and PHA recommendations. Coordinate with the EHS department to secure clearance before executing new products in the plant.

## Process Excellence & Optimization (OPEX)

- **Yield & Capacity Enhancement:** Led continuous improvement initiatives to enhance product yields, expand capacity, and drive production throughput in existing blocks.
- **Cycle Time Reduction:** Identified process bottlenecks and delay steps to minimize yield losses and optimize batch cycle times.
- **Solvent Management:** Optimized Solvent Recovery System (SRS) operations and implemented closed-loop washings to minimize solvent losses and lower fresh solvent consumption.
- **Energy & Utilities Auditing:** Managed plant energy audits and conducted detailed mass/energy balance studies to minimize utility consumption.
- **Lean Manufacturing:** Implemented 5S and Kaizen methodologies to foster a workplace culture of operational efficiency.

## Technology Transfer & Scale-Up

- **Process Scale-Up:** Scaled up newly developed API and intermediate processes from lab and pilot scale to commercial plant production.
- **Data Generation:** Generated critical engineering scale-up parameters in the lab, including mixing calculations, filtration rates, heating/cooling cycles, and addition times.
- **Batch Monitoring:** Coordinated and monitored validation, exhibit, and commercial trial batches at pilot and production scale.
- **Cross-Functional Coordination:** Liaised with R&D, QA, Regulatory, and production teams to secure seamless technology absorption, DMF filings, and timely plant startups.

- **Documentation Support:** Reviewed tech packs, CPHE reports, and engineering calculations while preparing process engineering dockets, validation protocols, and Batch Production Records (BPR).

## Technical Services & Troubleshooting

- **Equipment & Product Mapping:** Performed facility identification, circuit mapping, and equipment suitability assessments to de-clash product matrices.
- **Deviation Investigations:** Led root-cause investigations for product failures, deviations, Out of Specification (OOS), and Out of Trend (OOT) results to establish robust CAPAs.
- **Crystallization Monitoring:** Studied and monitored crystallization operations to achieve targeted polymorphs, particle size distribution, and eliminate process abnormalities.
- **Lifecycle Compliance:** Compiled daily observation logs, monthly variance metrics, Annual Review Reports (ARR), and Continuous Process Verification (CPV) data.

## Capital Projects & Engineering Design

- **P&ID & PFD Design:** Prepared Process Flow Diagrams (PFD), Piping & Instrumentation Diagrams (P&ID), and process data sheets for reactors, filters, dryers, and storage tanks.
- **Engineering Calculations:** Executed basic and detailed chemical engineering calculations for heat loads, line sizing, utility requirements, and pump or agitator specifications.
- **Equipment Qualification:** Drafted User Requirement Specifications (URS), technical data sheets, and equipment qualifications including DQ, IQ, and OQ.
- **Erection & Commissioning:** Supervised the erection, pre-commissioning, and commissioning of new manufacturing blocks, DCS automation systems, utility infrastructure, and effluent treatment systems like MEE and ATFD.
- **CAPEX & Cost Estimation:** Conducted project feasibility studies, raw material costing (RMC), and prepared detailed CAPEX estimations for upcoming facilities.

## Process Safety & EHS Compliance

- **Hazard Assessments:** Led Process Hazard Analysis (PHA), Quantitative Risk Assessments (QRA), Pre-Start Safety Reviews (PSSR), and HAZOP studies with cross-functional teams.
- **Safety Data Evaluation:** Evaluated reaction and powder safety data (RC1, DSC, MIE) to design and execute necessary risk mitigation controls.
- **Regulatory Compliance:** Maintained strict adherence to cGMP and safety norms, conducted routine safety audits, and updated Material Safety Data Sheets (MSDS).
- **Personnel Training:** Handled the training of production chemists and personnel on operational safety, critical process parameters, and hazardous raw material handling.